(c) whether it is a fact that the drugs on which these medicines are based have caused at least 15,000 deaths in U.K.;

(d) whether it is also a fact that these medicines are causing serious side effects and a number of countries have banned the marketing of these medicines as well as other products based on these drugs;

(e) whether any steps have been taken to ban these products in our country; and

(f) if not, what are the reasons therefor?

THE DEPUTY MINISTER IN THE DEPARTMENT OF FAMILY WELFARE (SHRI S. KRISHNA KUMAR): (a) and (b) Yes, Sir.

(c) and (d) The World Health Organisation had informed the member countries that the preparations containing Oxyphenbutazone and Phenylbutazone have been withdrawn from Norway, Israel, U.K., Finland, Zimbabwe, Jordan, United Arab Emirates and the use of these drugs in some countries has been restricted to the treatment of ankylosing spondylitis and gouty arthritis only. This action has been taken as a result of reported adverse reactions of aplastic anaemia, agranulocytosis due to these drugs resulting in deaths in some countries. We have no information on reports of 15,000 deaths in U.K. as claimed in the press report.

(e) and (f) The Indian Council of Medical Research and Indian Medical Association (IMA), were of the opinion that the drugs Oxyphenbutazone and Phenylbutazone are useful drugs and there is, therefore, no case of total withdrawal of these drugs from the market. However, the use of these drugs has been restricted for the treatment of ankylosing spondylitis and gouty arthritis only. Manufactureres of these drugs have been directed through their Association and the State Drug Control Authorities to incorporate precautions and contra-indication in the package inserts and in the promotional literature on these drugs.

Combination of Tranquillisers with Analgesics

2391. SHRI NAND KISHORE BHATT: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that combination of tranquillisers with analgesics are being marketed in our country;

(b) if so, the names of brands having such composition being marketed in our country alongwith the names of the manufacturers;

(c) whether Government are aware about the adverse effects of medicines containing tranquillisers with analgesics;

(d) if so, what are the details thereof;

(e) whether it is a fact that such a combination is not being marketed anywhere in the world;

(f) if so, what are the reasons for granting permission for such combination;

(g) whether such a permission was granted on the basis of clinical trials; and

(h) if so, what are the names of the institutions where the trials were conducted alongwith the details of the report in each case?

THE DEPUTY MINISTER IN THE DEPARTMENT OF FAMILY WELFARE (SHRI S. KRISHNA KUMAR): (a) Yes, Sir.

(b) As licences for manufacture and sale of formulations are granted by the State Drug Control Authorities, we do not have all the names of the formulations marketed in the country.

(c) and (d) Toxic effects are fatalities following over-dose of dextropropoxyphene alone or in combination

with other Central Nervous System depressants such as alcohol have been reported in other countries.

The "SCRIP" issue No. 978 dated the 4th March, 1985 has reported in the latest issue of Current problems (No. 14 of February 1985) from UK, CSM, had warned of the dangers of dextropropoxyphene related self poisoning and outlined precautionary measures to be considered by the doctors. According to the UK, CSM, "During the normal therapeutic use, dextropropoxyphene is rarely associated with serious adverse effects. However, when the therapeutic dose is exceeded the drug is extremely dangerous particularly in combination with alcohol and dextropropoxyphene is the commonest reported cause of drug induced death."

(e) To best of our knowledge, combination of analgesics with tranquillizers are being marketed in many countries including United Kingdom.

(f) to (h) As licences for manufacture and sale of formulation are granted by the State Drug Control Authorities, such combinations have been licensed to be manufactured and marketed by the respective State Drug Control Authorities long time back in consultation with medical experts.

Findings of U.S. Agency on Study of Arthritis Drugs

2392. SHRI NAND KISHORE BHATT: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government's attention has been drawn to the news item appeared in the 'International Herald Tribune' of 30th December, 1983 under the caption "U.S. Agency to study arthritis drugs that a group links to 10,000 deaths"

(b) if so, the names of these arthritis drugs and whether these drugs are being marketed in our country;

(c) The names of the medicines based on these drugs being marketed in India;

(d) whether Government are aware of the findings of U.S. Agency;

(e) if so, what are the details thereof;

(f) whether there are substitutes available to these drugs; and

(g) if so, what are the reasons for not banning marketing of these drugs in our country?

THE DEPUTY MINISTER IN THE DEPARTMENT OF FAMILY WELFARE (SHRI S. KRISHNA KUMAR): (a) This Ministry has no information on the news item which had appeared in 'International Herald Tribune' of 30th December, 1983.

(b) to (g) Do not arise.

Ban on the Ergot Combination

2393. DR. JOSEPH LEON D' SOUZA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government have banned the manufacture and sale of drugs in combination with Ergot;

(b) whether it is a fact that such combinations are dangerous and have adverse effects;

(c) whether it is also a fact that Migranil, Cafergot, Vasogrin and Migril belong to fixed combination with Ergot; and

(d) if so, the reasons for which these products are being allowed to be sold in the country and by when the sales will be withdrawn?

THE DEPUTY MINISTER IN THE DEPARTMENT OF FAMILY WELFARE (SHRI S. KRISHNA KUMAR): (a) and (d) This Ministry have issued a Notification prohibiting manufacture and sale of Fixed dose Combina-